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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/134,333	08/14/1998	SHIRLEY LONGACRE-ANDRE	0660-0135-0X	7863

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EXAMINER	
GRUN, JAMES LESLIE	
ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 03/20/2002

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/134,333	LONGACRE-ANDRE et al.
Examiner	**Art Unit**
James L. Grun, Ph.D.	1641

-- The MAILING DATE of this communicati n appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *20 Jun 2001*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *117-149* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *117-149* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on *14 Aug 1998* is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☒ Other: *Notice to Comply...Sequence Disclosures*

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1641.

The Request for a Continued Prosecution Application under 37 CFR § 1.53(d), filed 20 June 2001, is acknowledged and, as directed therein, the amendment filed 20 April 2001 has been entered. Claims 117-149 are newly added. Claims 68-116 have been cancelled. Claims 117-149 remain in the case. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This Application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). However, this application clearly fails to comply with the requirements of 37 CFR §§ 1.821 through 1.825 for at least the following reason(s), as also set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures: the sequence disclosed, e.g., on page 9, is not listed as required; the sequences listed on the paper and computer readable form of the "Sequence Listing" as SEQ ID NOs: 7 and 8 do not find support in Fig. 1C in the specification as filed, the sequences which the listed sequences are purported to list, thus the sequences disclosed in Fig. 1C are not listed in the "Sequence Listing" as required; and, the entry of "SEQ ID NO:" identifiers for every appearance of sequences in the description or claims of the patent application has not been directed as required.

Applicant is required to provide a substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification, which includes each of the sequences disclosed in the specification as required by 37 CFR § 1.821(c). A substitute copy of the "Sequence Listing" in computer readable form must be provided as required by 37 CFR § 1.821(e). Applicant must direct the entry of "SEQ ID NO:" identifiers for every appearance of sequences in the description or claims of the patent application. Applicant must also provide a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter as required by 37 CFR §§ 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d). Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR § 1.821(g).

A reply to a notice to comply with the sequence rules should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office.

Please direct all such replies to the United States Patent and Trademark Office via one (1) of the following:

1. Electronically submitted through EFS-Bio (<<**http://www.uspto.gov/ebc/efs/downloads/documents.htm**>>, EFS Submission User Manual - ePAVE)

2. Mailed to:
U.S. Patent and Trademark Office
Box Sequence, P.O. Box 2327
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3. Mailed by Federal Express, United Parcel Service or other delivery service to:
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4. Hand Carried directly to the Customer Window at:
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Arlington, Virginia 22202

The drawings are objected to for the reason(s) that multiple misnumbered Figs. 12 are found in the application. Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Submission of corrected drawings may no longer be held in abeyance pending the indication of allowable subject matter. Failure to take corrective action within the set period will result in **ABANDONMENT** of the application. Direct any inquiries concerning drawing review to the Drawing Review Branch at (703) 305-8404.

The disclosure is objected to because of the following informalities: the "Brief Description of the Drawings" does not contain a description of Figs. 12A through 12F as depicted on sheets 36/59 through 41/59 of the drawing sheets; page 4 contains a citation to a reference "(13)", yet no reference is so numbered on page 52; page 35, line 14, it is believed that

--I, II or III-- was intended; page 35, line 15, it is believed that --I, II and III-- was intended. Appropriate correction is required.

The amendment filed 22 October 1999 is objected to under 35 U.S.C. § 132 because it introduces new matter into the specification. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the sequences listed on the paper and computer readable form of the "Sequence Listing" as SEQ ID NOs: 7 and 8 do not find support in the specification as filed.

Applicant is required to cancel the new matter in the response to this Office action.

The specification is objected to and claims 117-149 are rejected under 35 U.S.C. § 112, first paragraph, for reasons similar to those of record, set forth with regard to the prior similar subject matter of claims 68-116, that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, and which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's arguments filed 20 April 2001 and entered 20 June 2001 have been fully considered but they are not deemed to be persuasive.

Applicant urges that the level of skill is high in this field of biotechnology and that the disclosures of Figs. 1A-1D and 2 illustrate various recombinant sequences useable in the invention. This is not found persuasive because, as set forth, the skilled artisan cannot envision the detailed chemical structures of the full scope of recombinant proteins encompassed by the rejected claims because one cannot conceive that which is not disclosed and which is only described by a statement that it is part of the invention and a reference to a potential method for isolating it. Furthermore, In *The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of molecules by only their functional activity does not provide an adequate written description of the genus. The court indicated that although applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of molecules falling within the scope of the claimed genus. Here, the disclosure of a few proteins is not found to representatively describe the full scope of the genus of recombinant MSP-1 fragments with unknown and unpredictable structures and properties. Note that it has also been decided that an enabling disclosure for the preparation and use of a single analog, or only a few analogs, of a product does not enable all possible analogs where, as here, the characteristics, such as the structure, of the analogs are unpredictable. Amgen Inc. v. Chugai Pharmaceutical Co. Ltd. (18 USPQ 2d 1027 (CAFC 1991)).

Applicant urges that the structures of several of the MSP-1 EGF-like domains were known and that these domains are taught as likely essential for the active principal. This is not

found persuasive because the claims are not limited to conformational epitopes found in the epidermal growth factor regions. Moreover, the source and reactivity of the antisera is not defined in such a manner that one, absent further description and guidance from applicant, would be apprised of which epitopes or antisera are predictably encompassed and functional and/or required in the invention.

Claims 119, 136, and 149 (dependent upon which active independent claim applicant intended the claim to depend from) are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, and which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant teaches the atomic coordinates in Annex II and the NMR fingerprints of Figs. 12.1A-12.1C as those of the MSP-1_{19} of *Plasmodium vivax* (see e.g. pages 35-36). Thus, applicant does not provide written description or enablement of any protein with the disclosed coordinates or fingerprints which is other than *Plasmodium vivax* as required by the instant claims. Absent such description, one would be unable to practice the invention as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 117-149 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 117-129 and 131-133, "the" surface protein 1, "the" merozoite form, "the" surface, and "the end of its penetration phase" lack antecedent basis. Two recitations of "wherein said C-terminal fragment remains anchored...during an infectious cycle" are redundant. The recitation of "human antisera" is entirely vague and indefinite because sufficient definition of source and reactivity of the antisera are lacking for one to know what antisera are encompassed. The interrelationships of the conformational epitopes and the two epidermal growth factor regions to the p19 fragment of MSP-1 or portion thereof are not clear.

In claim 119, "the" atomic coordinates and "the" NMR fingerprints lack antecedent basis.

In claim 120, it is not clear what in claim 117 is being further limited as the claim appears to limit the intended use of the protein rather than any clear structure of the protein.

In claim 121, "the" C-terminal region lacks antecedent basis and is unclear because it is unclear what is encompassed by "p33" or what "region" thereof is intended by applicant as encompassed.

Claims 122-125 are vague and indefinite because it is unclear what is encompassed by "p33" or what "region" thereof is intended by applicant as encompassed. It is not clear if the C-terminal region is part of the "essential constituent polypeptide" sequence.

In claims 123-125, "the" C-terminal region, "the" cleavage, and "the" same MSP-1 protein lack antecedent basis.

In claims 126 and 127, "said" polypeptide, "the" membrane, and "the" MSP-1 protein lack antecedent basis. It is not clear how a cell is infected with the protein or how infection of a cell with MSP-1 protein relates to a recombinant protein comprising a fragment of the protein as the "essential constituent polypeptide" sequence.

In claim 127, the relationship of having a glycosylphosphatidylinositol membrane anchoring group to being "hydrosoluble" is not clear.

In claim 128, "said" polypeptide and "the" amino acid sequence lack antecedent basis and are not clear as to what is encompassed.

In claim 129, "said" polypeptide and "the" amino acid sequence lack antecedent basis and are not clear as to what is encompassed.

In claim 130, "the" surface protein 1 and "the" merozoite form lack antecedent basis. The recitation of "human antisera" is entirely vague and indefinite because sufficient definition of source and reactivity of the antisera are lacking for one to know what antisera are encompassed. The interrelationships of the conformational epitopes and the two epidermal growth factor regions to the p19 fragment of MSP-1 or portion thereof are not clear.

In claims 134-144 and 148, "the" surface protein 1, "the" merozoite form, "the" surface, and "the end of its penetration phase" lack antecedent basis. Two recitations of "wherein said C-terminal fragment remains anchored...during an infectious cycle" are redundant. The recitation of "human antisera" is entirely vague and indefinite because sufficient definition of source and reactivity of the antisera are lacking for one to know what antisera are encompassed. The interrelationships of the conformational epitopes and the two epidermal growth factor regions to the p19 fragment of MSP-1 or portion thereof are not clear.

In claim 136, "the" atomic coordinates and "the" NMR fingerprints lack antecedent basis.

In claim 137, it is not clear what in claim 134 is being further limited as the claim appears to limit the intended use of the composition rather than any component of the composition.

In claim 138, "the" C-terminal region lacks antecedent basis and is unclear because it is unclear what is encompassed by "p33" or what "region" thereof is intended by applicant as encompassed.

Claims 139-142 are vague and indefinite because it is unclear what is encompassed by "p33" or what "region" thereof is intended by applicant as encompassed. It is not clear if the C-terminal region is part of the "essential constituent polypeptide" sequence.

In claims 140-142, "the" C-terminal region, "the" cleavage, and "the" same MSP-1 protein lack antecedent basis.

In claims 143 and 144, "said" polypeptide, "the" membrane, and "the" MSP-1 protein lack antecedent basis. It is not clear how a cell is infected with the protein or how infection of a cell with MSP-1 protein relates to a recombinant protein comprising a fragment of the protein as the "essential constituent polypeptide" sequence.

In claim 144, the relationship of having a glycosylphosphatidylinositol membrane anchoring group to being "hydrosoluble" is not clear.

In claim 148, it is not clear which, or if all, components of the composition are conjugated.

In claims 145-147, "the" surface protein 1 and "the" merozoite form lack antecedent basis. The recitation of "human antisera" is entirely vague and indefinite because sufficient definition of source and reactivity of the antisera are lacking for one to know what antisera are encompassed. The interrelationships of the conformational epitopes and the two epidermal growth factor regions to the p19 fragment of MSP-1 or portion thereof are not clear.

In claim 146, "said" polypeptide and "the" amino acid sequence lack antecedent basis and are not clear as to what is encompassed. A p19 sequence of MSP-1 protein from *Plasmodium falciparum* does not further limit a p19 fragment of MSP-1 protein of *Plasmodium cynomolgi*.

In claim 147, "said" polypeptide and "the" amino acid sequence lack antecedent basis and are not clear as to what is encompassed. The claim provides no further limitation of a p19 fragment of MSP-1 protein of *Plasmodium cynomolgi*.

Claim 149 depends from a cancelled claim. Moreover, "[t]he" vaccinating composition, "said" 19 kilodalton, "the" surface protein 1, "the" merozoite form, "the" atomic coordinates, and "the" NMR fingerprints lack antecedent basis. It is believed that --kilodalton-- and Fig. --12.2c-- were intended.

Claims 117-128, 133, and 149 are rejected under 35 U.S.C. 102(b) as being anticipated by Egan et al (Infection & Immunity 63(2): 456-466, Feb. 1995) for reasons of record in the prior rejection of the similar subject matter of claims 68-116.

Claims 119 and 149 rejected under 35 U.S.C. § 102(b) as being anticipated by Shi et al (Infection and Immunity 64(7): 2716-2723, July 1996), as evidenced in light of Egan et al (Infection and Immunity 65(8): 3024-3031, August 1997) for reasons of record in the prior rejection of the similar subject matter of claims 70 and 95.

Claims 119 and 149 rejected under 35 U.S.C. § 102(b) as being anticipated by Egan et al (Infection and Immunity 65(8): 3024-3031, August 1997) for reasons of record in the prior rejection of the similar subject matter of claims 70 and 95.

Claims 117-128, 133, and 149 are rejected under 35 U.S.C. 102(a) as being anticipated by Chang et al (Infection & Immun. 64(1): 253-261, Jan., 1996) for reasons of record in the prior rejection of the similar subject matter of claims 68-116.

Applicant's arguments filed 20 April 2001 and entered 20 June 2001 have been fully considered but they are not deemed to be persuasive. Applicant urges that the proteins of the prior art do not have the GPI anchor. This is not found persuasive because the argued limitation is not found as a limitation of the subject matter as instantly claimed. The examiner would note that malarial parasites penetrating into erythrocytes do not make the "recombinant" protein, soluble or otherwise, and that the properties of that product of nature are of no moment with regard to the recombinant protein as claimed. Moreover, the examiner would note that the protein isolated for the relevant determinations of coordinates and fingerprints in the instant specification (see e.g. page 38) was also the soluble form lacking the anchor (i.e. that purified from culture supernatants). Applicant urges that the recombinant proteins of the prior art, comprising the sequence of the p19 fragment, do not have the conformational data as disclosed and claimed. This is not found persuasive because the structure of the recombinant protein is not limited as argued because the conformational structure is merely recited as a property for the fragment, inherent to the proteins of the references comprising the essential sequence of the fragment as claimed.

Claims 117-120, 126-128, 131, and 132 are rejected under 35 U.S.C. § 102(b) as being anticipated by Murphy et al (Parasitology 100: 177-183, 1990) in light of Blackman et al (FEMS Immunology and Medical Microbiology 6: 307-316, 1993). This is a NEW GROUND of rejection.

Murphy et al disclose the s42 and s42ΔA proteins which comprise the "essential polypeptide sequence" as instantly claimed, including the two epidermal growth factor regions of the C-terminal p19 region of the MSP-1 protein of *Plasmodium falciparum*. The proteins were isolated by electrophoretic techniques and were shown, in unreduced form, to bind antibodies in human immune serum (in light of Blackman et al (1993)). The examiner would note that malarial parasites penetrating into erythrocytes do not make the "recombinant" protein and that well known properties of a portion of the protein in nature are not found to limit the claimed "recombinant" protein.

Claims 117-120, 128, 131, and 132 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Blackman et al (FEMS Immunology and Medical Microbiology 6: 307-316, 1993).

Blackman et al disclose the s42ΔA protein which comprises the "essential polypeptide sequence" as instantly claimed, including the two epidermal growth factor regions of the C-terminal p19 region of the MSP-1 protein of *Plasmodium falciparum*. The protein was purified by affinity chromatography and was shown, in unreduced form, to bind antibodies in human immune serum. Dimers of the antigen are disclosed (see e.g. Fig. 3). The examiner would note that malarial parasites penetrating into erythrocytes do not make the "recombinant" protein and that well known properties of a portion of the protein in nature are not found to limit the claimed "recombinant" protein.

Claims 134-136, 138-142, 144, and 148 are rejected under 35 U.S.C. § 102(a) as being anticipated by Burghaus et al (Infection and Immunity 64: 3614-3619, Sept 1996).

Burghaus et al incorporated the correctly folded 19 kDa C-terminal fragment of *P. falciparum* MSP-1 expressed as a fusion protein into a vaccinating composition with alum. The C-terminal fragment or portion thereof inherently have the well known properties ascribed thereto by the claims. The examiner would note that the subject matter has not been accorded the benefit of the filing date of the French priority document because, as seen in the certified translation thereof provided by applicant, this document is silent on vaccinating compositions comprising alum.

Claims 117-127, 129, 130, and 149 are rejected under 35 U.S.C. 103(a) as being unpatentable over Longacre (Mol. Biochem. Parasitol. 74: 105-111, 1995) in view of Longacre et al (Mol. Biochem. Parasitol. 64:191, 1994).

Longacre teaches the cloning of the *Plasmodium cynomolgi* C-terminal MSP-1 protein sequence in a construct similar to that previously shown effective by Longacre et al (Mol. Biochem. Parasitol. 64:191, 1994) for the cloning of the C-terminal p42 and p19 fragments of the *P. vivax* MSP-1 protein in baculovirus. The reference suggests the use of the fragments for vaccine studies. The reference does not specifically teach protein production and isolation.

Longacre et al (Mol. Biochem. Parasitol. 64:191, 1994) teach recombinant baculovirus constructs comprising nucleic acid sequences encoding fragments of the *Plasmodium vivax* MSP-1 protein which produce, in infected insect cells, either anchored or secreted forms of both the C-terminal p42 fragment (which comprises the C-terminal p19 fragment) and the C-terminal p19 fragment of the *P. vivax* MSP-1 protein. The reference admits that the construction of recombinant baculovirus expressing *P. vivax* MSP-1 protein fragments was guided by the previous functional constructs expressing *P. falciparum* MSP-1 protein fragments. The reference demonstrates that baculovirus constructs containing an appropriate MSP-1 signal sequence can be used for the expression of various length soluble or anchored C-terminal fragments of the MSP-1 protein.

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have used the baculovirus construct encoding the *Plasmodium cynomolgi* C-terminal MSP-1 protein sequence, or similarly constructed baculovirus constructs as taught in Longacre et al, in Longacre for the production and isolation of encoded protein because Longacre desires the protein for vaccine studies and Longacre et al teach that such constructs had been successfully used for protein production and isolation of the homologous fragments from a number of other species of malarial parasite for such studies. One would have had an extremely reasonable expectation of success in view of the prior success with the homologues from the other species of *Plasmodium* taught in Longacre et al.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Chang et al (J. Immunology 149: 548-555, 1992) disclose baculovirus constructs comprising nucleic acid sequences encoding the C-terminal p42 fragment of the *Plasmodium falciparum* MSP-1 protein.

Chappel et al (Mol. Biochem. Parasitol. 60:303, 1993) teach one of the recombinant baculoviruses of Murphy et al, similar in construction to that as instantly disclosed, i.e. having the amino terminal 34 amino acids of the *P. falciparum* MSP-1 protein fused to 271 amino acid residues of the p42 fragment of the protein ending at residue 1723 of the sequence as disclosed and numbered in Miller et al ((Mol. Biochem. Parasitol. 59:1, 1993; see page 6), which produces a soluble protein (because it lacks the putative glycosylphosphatidylinositol addition region C-terminal to the second EGF-like domain) and which includes both EGF-like domain structures of the p19 fragment of the MSP-1 protein. The reference teaches that the first EGF-like domain of the p19 fragment, by itself, contains many of conformational epitopes recognized by known antibodies which bind to both the p42 and p19 fragments and inhibit parasite growth.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (703) 308-3980. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (703) 305-3399.

The phone numbers for official facsimile transmitted communications to TC 1600, Group 1640, are (703) 872-9306, or (703) 305-3014, or (703) 308-4242. Official After Final communications, only, can be facsimile transmitted to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. The above inquiries, or requests to supply missing elements from Office communications, can also be directed to the TC 1600 Customer Service Office at phone numbers (703) 308-0197 or (703) 308-0198.

James L. Grun, Ph.D.
March 19, 2002

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641

Application No.: 09/134,333

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- [X] 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations.
- [ ] 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- [ ] 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- [ ] 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- [ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- [ ] 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- [X] 7. Other: All disclosed sequences are not listed as required by 37 CFR § 1.821(c), because the sequences disclosed on page 9, line 12, and in Fig. 1C do not appear in either the CRF or the paper copy of the "Sequence Listing". Also, "SEQ ID NO:" identifiers must be entered as required by 37 CFR § 1.821(d), for example at least in the brief description of a Fig. depicting a sequence.

Applicant Must Provide:

- [X] An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- [X] An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- [X] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).
- [X] Amendments to the specification directing entry of "SEQ ID NO:" identifiers into the specification.

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
PatentIn Software Program Support (SIRA)
Technical Assistance.....703-287-0200
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